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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,482	04/06/2005	Katsuaki Miyaji	268038US0PCT	5300

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EXAMINER	
LOEWE, SUN JAE Y	
ART UNIT	**PAPER NUMBER**
1609	

NOTIFICATION DATE	DELIVERY MODE
07/10/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/530,482	MIYAJI ET AL.	
	Examiner	Art Unit	
	Sun Jae Y. Loewe	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-74* is/are pending in the application.

4a) Of the above claim(s) *41-50,52-54,58-67 and 69-71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-40,51 and 72* is/are rejected.

7)☒ Claim(s) *55-57,68,73,74* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/17/05 and 4/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of synthetic example 56 in the reply filed on June 18, 2007 is acknowledged. The traversal is on the ground(s) that the restriction requirement is improper because reasons to support patentable distinctness for the species were not presented. This is not found persuasive for the following reason.

MPEP § 808.01(a) is referenced to indicate impropriety of the restriction requirement. Applicants are reminded that the requirements for insisting upon restriction set forth in MPEP § 808.01(a) are for national applications filed under 35 USC 111 (a), see MPEP § 801. The instant application is a national stage application (35 USC 371), therefore the guidelines set forth in MPEP § 1893.03(d) for Unity of Invention were followed. The restriction requirement stated, with appropriate support, that the species generically claimed lack unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

2. The search and examination was initially performed for the elected species of synthetic example 56, which was allowable over the prior art (see Section 8). However, the claims drawn to the process of using the elected species did not meet the requirements of 35 USC 112. Further, non-elected species which anticipate the generic claims were found in the prior art (see Section 7). Therefore, based on the provisions of MPEP § 1893.03(d), non-elected species were not rejoined for further search and examination.

¶ *18.20 National Stage Election of Species in 35 U.S.C. 371 Applications*

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. Claims 41-50, 52-54, 58-67 and 69-71 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 18, 2007.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on June 17, 2005 and April 6, 2005 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statement was considered. Signed copies of form 1449 are enclosed herewith. For the following documents, the full English language translations were not provided, thus only the abstracts were considered: JP 10-072492, JP 11-001477, JP 11-152276, WO 01/07423, JP 2001-097948.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 72 rejected under 35 U.S.C. 112, first paragraph for the following reasons. The specification is enabling for making therapeutic agent for immune thrombocytopenic purpura and chemotherapy induced thrombocytopenia (Jelic et al. abstract; Michel, abstract). The specification is not enabling for making:

a) preventative/improving agents
b) therapeutic agents for diseases other that those noted above

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8USPQ2s 1400, 1404 (Fed. Cir. 1988). MPEP 2164.01(a) states "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue". The factors are applied below to the instant claims.

The breadth of the claims
The claim is broadly drawn to preventive, therapeutic or improving agent for diseases against which activation of the thrombopoietin receptor is effective.

The nature of the invention
The elected species is disclosed to activate thrombopoietin receptor. Based on art recognized correlation, see for example Jelic et al. (abstract), agonism and activation of the receptor are extended promote the increasing of platelets.

The state of the prior art/level of ordinary skill/level of predictability
Thrombocytopenia:

- The method of treating thrombocytopenia, the condition where the amount of platelets is lowered (http://www.tirgan.com/ thrpenia.htm, page 1), depends on the cause/etiology of the disease (see for example, http://www.tirgan.com/ thrpenia.htm, page 8; Jelic et al. abstract).
- Secondary thrombocytopenia is platelet lowering due to infections. For this etiology the underlying condition must be treated in order to achieve treatment of the thrombocytopenia. One example of such condition is that resulting from HIV infection (Sundell et al., abstract). The art recognized treatment of HIV currently involves protease inhibitors and one chemokine inhibitor in phaseII/III clinical development (Simon et al., p. 494 Table 2 and p. 495 Table 3). Therefore, a correlation does not currently exist between activating thrombopoietin and treating thrombocytopenia resulting from HIV infection. It follows that correlation between activating thromobopoietin and preventing thrombocytopenia resulting from HIV infection also does not exist.
- Platelet transfusions remain the only secure means to acutely increase the platelet count in patients with imminent or actual bleeding due to thrombocytopenia caused by chemotherapy (Jelic et al., abstract; Michel, abstract). Thus, a correlation between thrombopoietin activation and prevention/improvement of thrombocytopenia resulting from chemotherapy does not currently exist.
- Thrombocytopenia can result from adverse reaction to drugs. Thus, prevention/improvement based on this etiology would require stopping the medication (http://www.tirgan.com/ thrpenia.htm, page 9-10).
- Similarly, correlation between activating thrombopoietin and preventing/improving other conditions encompassed by the instant claims, not specifically described here, do not currently exist.

The amount of direction provided by the inventor/existence of working examples
No direction/working examples, in addition to the disclosure of the thrombopoietin activating species, is provided in the specification.

The quantity of experimentation needed to make or use the invention
In the absence of working examples and in the absence of a nexus between prevention/improvement of the conditions encompassed by the claims, one of ordinary skill is not enabled by the disclosure to make the preventive/improving agent. The quantity of experimentation needed is undue.

Claim Rejections - 35 USC § 102

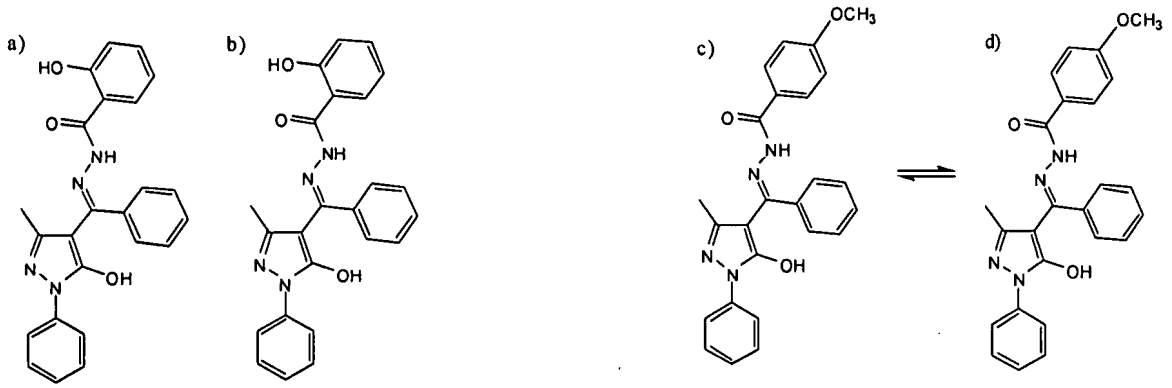
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 38-40 and 51 rejected under 35 U.S.C. 102(b) as being anticipated by Rao et al. (for example, ligand designated 2a on page 1828, published 1997, see Scheme 1a), as evidenced by Liu et al (Figure 1, p. 742).

Scheme 1



Rao et al. Liu et al.

The compound disclosed by Rao et al. (Scheme 1a) is a tautomer of the compound wherein A=R^1=R^{12}=phenyl; B=R^2=R^{13}=methyl; D=R^3=R^{14}=phenyl; E=R^4=R^{15}=hydroxyl substituted phenyl (Scheme 1b). The existence of the form shown in Scheme 1b is evidenced by the disclosure of Liu et al. (Scheme 1c/1d). The compounds of Scheme 1a and Scheme 1b anticipate the instant claims.

Allowable Subject Matter

8. The prior art does not anticipate or make obvious the elected species of synthetic example 56.

Conclusion

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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